

## REMARKS

Claims 1-41 and 51-56 are pending in the present application. Claims 1-41 and 51-56 are hereby cancelled without prejudice or disclaimer. New claims 57-68 are hereby added. Support for the new claims can be found in original claims 1-7, 13-16, 18-21, 23-26, 28-31, 33-36, and 54-56.

### Rejections Under 35 U.S.C. 112, Second Paragraph

Claims 51-56 are rejected under 35 U.S.C. 112, second paragraph as indefinite. Claims 51-56 have been cancelled, and therefor the rejection is moot. However, new claims 65-68, claiming an oil comprising a sterol ester composition and tracking original claims 54-56, have been added. Applicants respectfully disagree with Examiner as to whether the phrase “a **free** sterol level of less than 10%” is indefinite. Page 4, line 4 of Applicants’ specification clearly defines “free” with respect to sterols as unesterified. Applicants, however, have drafted new claims 65-68 to recite “unesterified” sterols rather than “free” sterols in order to further prosecution.

### Rejections Under 35 U.S.C. 103(a)

Claims 1-41 and 51-56 are rejected under 35 U.S.C. 103(a) as unpatentable over Miettinen *et al.* (US Pat. No. 5,502,045, hereinafter referred to as “Miettinen”) and Wester *et al.* (WO 99/565558, hereinafter referred to as “Wester”) in view of Letton *et al.* (US Pat. No. 5,306,516, hereinafter referred to as “Letton”) and Dickson *et al.* (US Pat. No. 5,869,304, hereinafter referred to as Dickson). Claims 1-41 and 51-56 have been cancelled without prejudice or disclaimer rendering rejection of these claims moot. New claims 57-68 recite a clear, edible oil comprising more than about 10% of a sterol ester composition, wherein the sterol ester composition comprises more than 50% monounsaturated fatty acid moieties. Applicants submit that for the reasons stated herein, new claims 57-68 are patentable over Miettinen and Wester in view of Letton and Dickson.

Neither Miettinen nor Wester, or a combination thereof, in view of Letton and Dickson, teach or suggest an edible oil containing 10-30% sterol esters, wherein more than 50% of the fatty acid moieties in the sterol esters are monounsaturated fatty acid (MUFA) moieties, and

wherein the sterol ester-containing oil remains clear and non-cloudy at room temperature as recited in claims 57-68. Furthermore, these references do not provide the requisite motivation for combination, nor is there a reasonable expectation of success if these references are combined.

Although Miettinen recites  $\beta$ -sitostanol ester compositions and use of those compositions in an edible oil, Miettinen does not suggest a desired ratio of monounsaturated, polyunsaturated, and saturated fatty acid moieties for preparing the  $\beta$ -sitostanol ester compositions. Moreover, Miettinen specifically limits the amount of the  $\beta$ -sitostanol ester compositions to 3% and 6% by weight, in edible oils. *See*, Miettinen, column 6, example 3, lines 20-26. Applicants point out in their application that one problem with the prior art is that the solubility of prior art sterol and stanol ester compositions is less than desirable for delivery of an efficacious amount of the sterol esters in a “clear, non-opaque, appealing edible oil.” *See*, Applicants’ specification, page 4, lines 16-18. In contrast to Miettinen’s teaching of 3% and 6% stanol esters in an edible oil, Applicants claim edible oils containing 10-30% sterol esters.

Wester recites sterol ester compositions wherein more than half of the fatty acid moieties are polyunsaturated fatty acids, and use of those compositions in an edible oil. *See*, Wester, page 5, lines 5-9. Wester also teaches that using a high level of polyunsaturated fatty acids is the very factor that allows him to use higher sterol ester levels than the prior art. *See*, page 5, lines 5-12:

The present invention is based on the finding that sterol and/or stanol fatty acid ester compositions, in which more than 50% of the fatty acid moieties comprises polyunsaturated fatty acids (PUFA), preferentially more than 60% and more preferred more than 65% . . . show basically no texturing properties and thus can be used in food products were such a texturizing effect is due to product quality or production technology reason is undesirable. . . . (emphasis added)

Wester continues by explaining that stanol fatty acid esters with a high concentration of unsaturated fatty acids, mainly monounsaturated, gave an undesirable melting curve, wherein the stanol fatty acid esters have co-crystallized, as measured by differential scanning calorimetry. *See*, Wester, page 5, lines 14-17. Moreover, Wester teaches the desirability of using PUFAs when preparing sterol ester compositions, and the undesirability of using MUFAs when preparing sterol ester compositions. *See*, Wester, page 5, lines 14-38.

Letton is cited for the teaching that “fatty acid radicals can be used singly or in mixtures with each other in all proportions” as motivation to employ 50% MUFAs as the fatty acid moieties in the composition herein. Letton is further cited for the proposition that mono and/or di-unsaturated fatty acids are desirable because of their oxidative stability. The invention of Letton, however, is quite different from the Applicants’ claimed clear edible oil containing 10-30% of a sterol ester composition. Letton is concerned with shortening, which is opaque. Applicants are concerned with an oil, specifically clear oil. Letton is concerned with making polyesters of sugars, and making a shortening from the polyester polyols. Applicants are concerned with making esters of phytosterols and adding the sterol esters to an oil, while maintaining clarity in the oil mixture. Letton is concerned with the preparation of polyesters of polyols to make non-digestible shortening. Applicants are concerned with the preparation of esters of plant sterols so that the plant sterol esters can be adequately dissolved in edible oil and thus have a clear, edible oil containing an efficacious amount of sterol ester to be delivered to someone consuming the oil. Moreover, Letton does not address our problem—Letton is concerned with making a shortening; Letton is not concerned with making a clear edible oil. One of ordinary skill in the art would not look to Letton for guidance in making clear, edible oils. One of ordinary skill in the art would not be motivated to combine the teachings of Letton and Miettinen and Wester.

Moreover, even if one did combine the teachings of Letton with the teachings Wester and Miettinen, one still would not achieve Applicants’ claimed invention. Rather, a combination of the teachings of Letton with those of Wester and Miettinen would lead one to make sterol ester compositions wherein the majority of the fatty acid moieties are diunsaturated fatty acids, not monounsaturated fatty acids, as claimed by Applicants.

Stated otherwise, the relevant teachings of Letton, as pointed out by the Examiner, are: (1) one could use any combination of monounsaturated fatty acids, polyunsaturated fatty acids, and saturated fatty acids, when forming polyesters, and (2) it is known that either monounsaturated fatty acids or diunsaturated fatty acids will provide better oxidative stability than higher saturated polyunsaturated fatty acids. See Letton, column 5, lines 36-38. Miettinen shows that  $\beta$ -stanol ester compositions can be added to oils, though in much lower concentrations than claimed by Applicants. Miettinen, column 6, example 3 shows  $\beta$ -stanol

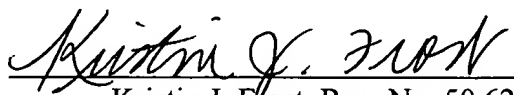
esters added to oil at 3% and 6% by weight. Wester shows that by preparing sterol esters polyunsaturated fatty acids, preferably with more polyunsaturated fatty acids than naturally occurs in high-PUFA oils, provides better melting profiles and less texturizing properties than monounsaturated or saturated fatty acids, and therefor can be added to oils or foods in higher quantities than sterol esters prepared with relatively higher monounsaturated or saturated fatty acids. Wester, page 5, first full paragraph, and page 5, lines 33-38. The logical combination of the references, then, would be a sterol ester composition wherein more than 50% of the fatty acids are diunsaturated. This would provide both oxidative stability, as taught in Letton, and a way to achieve a higher concentration of sterol esters than taught in Miettinen without the undesirable texturizing properties associated with monounsaturated fatty acids as taught in Wester. This combination, however, is different from Applicants' claimed oil containing 10-30% sterol esters, wherein more than 50% of the fatty acid moieties in the sterol ester composition are monounsaturated.

Finally, Dickson is cited for the proposition that "diets rich in saturated fatty acids are associated with increased risk of coronary artery disease whereas monounsaturated fatty acids are associated with decreased risk." Dickson, column 1, lines 21-23. That statement from Dickson is concerned with diet. It is not concerned with clear, edible oils containing 10-30% sterol esters. Furthermore, taken in combination with the teachings of Miettinen, Wester, and Letton, there is no reasonable expectation of successfully making a clear, edible containing sterol fatty acid esters wherein more than 50% of the fatty acid moieties are MUFAs.

Since combination of the references does not yield the claimed oil containing 10-30% sterol esters, wherein the sterol fatty acid esters comprise more than 50% MUFAs, Applicants submit that new claims 57-68 are patentable over the prior art of record. A prompt notice to that effect is respectfully requested.

Respectfully submitted,

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